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EXAMINER	
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ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/489,982	Applicant(s) STOLL ET AL.	
	Examiner Carolyn M Bleck	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 12 June 2003. Claims 1-20 are pending. Claims 1, 5, 7, 14, and 20 were amended. It is noted that Applicant states that claim 20 is new. However, claim 20 was a pending claim. Therefore, it is assumed that original claim 20 is being amended to include the limitations presented in the present Office Action.

Specification

2. The amendment filed 13 June 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly added recitation of the steps:

- encrypting prescription data defining a prescription so that the data would be indecipherable without appropriate computer decryption software;
- decrypting said prescription data from indecipherable form into a form that would be decipherable;
- wherein the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact; and
- said data being in a wholly intangible form

appears to constitute new matter within claim 1. Furthermore, claims 7 and 14 recite variations of these steps. Applicant does not point to, nor was the Examiner able to find any support for encryption/decryption software or "data transfer that occurs without physical contact" within the specification as originally filed. As such, Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims. Furthermore, it is suggested that the Applicant provide claim language which reflects the terminology found within the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

3. Claim 14 is objected to because of the following informalities: at line 12 of claim 14, it appears "intelligible" is grammatically incorrect. For the purposes of applying prior art, "intelligible" is being interpreted as "unintelligible." Appropriate correction is requested.

Claim Rejections - 35 USC § 112

4. Claims 1, 7, and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and for the reasons set forth in the objection to the specification above.

Independent claims 1, 7, and 14 recite limitations that are new matter, as discussed above.

Claims 2-6, 8-13, and 15-20 incorporate the deficiencies of independent claims 1, 7, and 14, through dependency, and are also rejected.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

NOTE: The following rejections assume that the subject matter added in 10 June 2003 amendment are NOT new matter, and are provided hereinbelow for Applicant's consideration, on the condition that Applicant properly traverses the new matter objections and rejections made in preceding sections above in the next communication sent in response to the present Office Action.

6. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich et al. (4,835,372) in view of Leigh-Spencer et al. (5,602,802), for substantially the same reasons given in the previous Office Action (paper number 12), and further in view of Computer Science Telecommunication Board (For the Record Protecting

Electronic Health Information, Computer Science Telecommunication Board National Research Council, National Academy Press, Washington, DC, July 1997).

(A) As per claim 1, 6, 11-12, Gombrich discloses a method for providing accurate identification of a patient and for items relating to a patient such as drugs (col. 1 lines 9-17 and col. 2 lines 36-45) comprising:

(a) providing a portable handheld patient terminal (PHPT) with a bar code reader to provide the main data collection component of patient identification information, wherein the PHPT allows storage of data relating to patients in memory (reads on "write"), wherein the PHPT utilizes infrared (IR) transmission/reception by an infrared transmitter/receiver arrangement or interface to transmit or send data stored in memory (reads on "read) (col. 3 line 59 to col. 4 line 20, col. 5 line 18 to col. 6 line 11, col. 10 line 57 to col. 11 line 5, col. 12 lines 14-66, col. 23 line 11-36);

(b) receiving at the PHPT (also called the bar code reading device) prescription information through the interface, wherein prescription information includes a recommended dosage and time to administer drugs entered by a staff member, secretary, or nurse (reads on "by a prescriber") (col. 15 line 51 to col. 16 line 17, col. 17 line 37 to col. 18 line 2, col. 26 lines 59-68, and col. 34 line 56 to col. 35 line 24);

(c) downloading from memory of the PHPT data via the communications port, wherein the data includes drug information, such as drugs administered (col. 24 lines 11-36); and

(d) filling the prescriptions at a pharmacy (col. 14 line 65 to col. 15 line 48).

Gombrich fails to disclose transferring a carrier by a patient to a pharmacy and downloading information *at the pharmacy*. Leigh-Spencer includes a programmable reminder system for medications where the prescribing pharmacist has the ability to program a simple portable module carried by the patient, wherein the programming of the module occurs when the pharmacist is filling a patient's prescription, wherein the patient carriers the module to the pharmacy, and wherein a two-way communication link is provided between the portable module and the programming station of the pharmacist (col. 3 lines 20-53, col. 2 lines 15-30, and col. 8 lines 6-40 and).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the aforementioned components of Leigh-Spencer within the method of Gombrich with the motivation of providing an efficient and cost-effective distribution of portable modules for use by patients and pharmacists (Leigh-Spencer; col. 2 lines 40-50) and ensuring patient's receive quality care by ensuring patient receive the proper prescription drugs at the proper time (Gombrich; col. 1 lines 47-60).

Claim 1 has been amended to include the newly added steps of "encrypting prescription data defining a prescription so that the data would be indecipherable without appropriate computer decryption software," "decrypting said prescription data from indecipherable form into a form that would be decipherable," and "wherein the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact."

Gombrich does not expressly disclose the encryption and decryption steps. However, Gombrich teaches providing for a security mechanism for prescription information. In particular, Gombrich includes providing limited access to Gombrich's system by logic means for verifying a user ID and patient ID checks and for providing an indication at a patient terminal means of the result of the verification (col. 2 lines 50-55, col. 46 lines 23-27).

Computer Science Telecommunication Board teaches in a health care setting in a health care information system, encrypting chunks of information (components of the patient record, including text, laboratory results, and images) by a server through software when the information is transmitted over a network such as the Internet, and then decrypting the chunks of information by special access software to allow viewing of the information, wherein the software is designed to only allow accessing and viewing of the information by receipt of properly authenticated user credentials (reads on "indecipherable without appropriate computer decryption software") (pp. 86-89, pp. 106-108, pp.120-122).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the encryption and decryption techniques disclosed in Computer Science Telecommunication Board within the method taught collectively by Gombrich and Leigh-Spencer with the motivation of controlling the use of information in order to protect the privacy of patients (Computer Science Telecommunication Board, pg. 12, 120) and providing limited access to a system (Gombrich; col. 2 lines 50-55).

As per the recitation of "wherein the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact," it is respectfully submitted that Gombrich teaches the input and output of data using infrared communication or RF communication (col. 10 line 57 to col. 11 line 51, col. 24 lines 11-36), wherein the RF signals allow for real time data transmission using an RF transceiver and antenna arrangement. The input and output of data using infrared or RF signals or infrared are wireless as evidenced by Gombrich (col. 23 15-20), and thus these wireless communication protocols are considered to be a form of "the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact."

(B) As per claim 2, Gombrich discloses entering an ID and password prior to accessing the PHPT to receive information at the PHPT (col. 16 lines 3-17, col. 17 line 37 to col. 18 line 2, col. 26 lines 59-68, col. 34 line 56 to col. 35 line 24, and col. 37 line 22 to col. 40 line 2).

(C) As per claim 3, Gombrich discloses storing and displaying upon request six to ten previously recorded and administered PRN or other controlled drug administered and the times they were administered in the bar code reading device (col. 2 lines 41-45, col. 3 lines 10-18, col. 3 lines 47-53, col. 5 lines 36-48, col. 14 lines 40-64, col. 16 lines 49-55, and col. 24 lines 11-36) and providing a green status light or other appropriate indication on the LCD display of the bar code reading device when a drug is

administered and automatically recording the drug was administered, and pushing a button on the bar code reading device if the treatment did not occur (col. 16 line 67 to col. 17 line 29).

Gombrich is entirely silent as to operating a digital clock/calendar within the carrier to generate internal values of time and date, providing the carrier with a prescription compliance switch interfaced to the clock/calendar, and operating a compliance switch by a patient upon taking a medication specified by the prescription.

Leigh-Spencer includes:

a clock within a portable module to program the current time of day and the specific times for each alarm, wherein a set alarm module of the programming station sets the portable module alarm times, wherein the set alarm module has a number of doses command and time of dose command for determining the portable module times (col. 2 lines 48-50, col. 8 lines 56-67, col. 10 lines 31-40 and 50-52, col. 11 lines 61-65, col. 13 lines 7-12);

a push button within the portable module, wherein a microprocessor is provided for receiving and storing alarm information and for providing visual and auditory alarms signals to a sound device and LED and for receiving an alarm silence signal from the push button (Fig. 1 and 6A, col. 6 lines 17-40, col. 11 lines 14-35); and

providing an auditory alarm warning to a patient that it is time to take a prescribed medicine, wherein the alarm is silenced by the patient by pushing the push button (col. 3 lines 34-36, col. 5 lines 14-16, col. 10 line 66 to col. 11 line 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the aforementioned features of Leigh-Spencer within the method of Gombrich with the motivation of increasing the effectiveness of treatment and reducing harm to a patient by providing a reminder device to ensure a patient follows the administration instructions of medication, including the specific time of day and dose of medication the patient should take (Leigh-Spencer; col. 1 lines 15-25).

(D) As per claim 4, Gombrich discloses providing an alert if a particular drug administration is overdue and/or improper at a portable bar code reading device (col. 2 line 67 to col. 3 line 4 and col. 17 lines 37-59).

Gombrich fails to expressly disclose providing a carrier with an annunciator element, entering into the carrier by the pharmacist, schedule data defining a prescription schedule comprising a plurality of sets of schedule times and dates at which a patient is to take a medication specified by a prescription, periodically comparing within the carrier the internal values of time and date with the schedule time and dates, and activating the annunciator element upon the internal values of time and date matching a set of schedule time and schedule date.

Leigh-Spencer discloses:

alarms including amplifiers, large flashing lights, and/or vibrators for patients within the portable module (Fig. 6A, col. 7 line 60 to col. 8 line 3);

downloading alarm instructions to the module microprocessor from the programming station communication interface to the module communication

interface by a pharmacist, wherein alarm instructions provide specific times of day for taking the medication (Fig. 1 and 6D, col. 1 lines 5-15, col. 2 lines 15-30, col. 2 lines 40-45, col. 4 lines 18-34, col. 5 lines 29-33, col. 6 lines 29-40, col. 8 lines 7-15, col. 9 line 52 to col. 10 line 23, col. 11 lines 45-50);

providing an alarm timer that provides a "time-of-day" alarm which will continue until the alarm is acknowledged by the patient in order to provide specific times of an alarm and to help ensure compliance with the reminder, wherein the programming station includes a set alarm module for setting the portable module alarm times and the set alarm module has a number of does command and time of dose command for determining the portable module alarm times, wherein the module microprocessor generates an alarm signal corresponding to the alarm instructions (time the dosage is due) (col. 2 lines 20-25, col. 3 line 62 to col. 4 line 2, col. 4 lines 33-35, col. 9 lines 31-40, 13 lines 8-11).

As per the step of comparing internal values of time with schedule times and dates, it is noted that in order to detect an alarm signal is needed such as that disclosed in Leigh-Spencer, it would be required by the portable module to provide a comparison between the alarm instructions (i.e., time of a dosage) with the internal time of the carrier to detect the alarm times.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the aforementioned features of Leigh-Spencer within the method of Gombrich with the motivation of increasing the effectiveness of treatment

and reducing harm to a patient by providing a reminder device to ensure a patient follows the administration instructions of medication, including the specific time of day and dose of medication the patient should take (Leigh-Spencer; col. 1 lines 15-25) and increasing compliance with the reminder device (Leigh-Spencer; col. 2 lines 15-30).

(E) As per claim 5, Gombrich discloses entering a user barcode ID prior to downloading from memory of the PHPT data via the communications port (Fig. 14, col. 16 lines 3-57, col. 24 lines 11-36, and col. 37 line 22 to col. 40 line 2).

(F) Claim 7 differs from claim 1 by reciting the following steps "entering a first access code into said carrier to enable software access" and "entering a second access code into the carrier to enable software access." As per these steps, Gombrich discloses:

(a) entering an ID and password prior to accessing the PHPT to receive information at the PHPT using software (Fig. 14, col. 16 lines 3-17, col. 17 line 37 to col. 18 line 2, col. 26 lines 59-68, col. 34 line 56 to col. 35 line 24, and col. 37 line 22 to col. 40 line 2); and

(b) entering a user barcode ID prior to downloading from memory of the PHPT data via the communications port (Fig. 14, col. 16 lines 3-57, col. 24 lines 11-36, and col. 37 line 22 to col. 40 line 2).

As per the recitation of "said data being in a wholly intangible digital form," Gombrich discloses information stored in appropriate data files contained in computer

system memory (col. 22 lines 41-43). It is respectfully submitted that data stored in computer memory is data in "digital form".

The remainder of claim 7 repeats the same limitations as claim 1, and is therefore rejected for the same reasons given above, and incorporated herein.

(G) Claims 8-10 and 13 repeat the same limitations as claims 3-4, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

(H) As per claims 14 and 19, Gombrich discloses a system for providing accurate identification of a patient and for items relating to a patient such as drugs (col. 1 lines 9-17 and col. 2 lines 36-45) comprising:

(a) a housing (col. 4 line 63 to col. 5 line 1-2);

(b) a programmed microprocessor (col. 12 lines 14-66);

(c) an LCD display and keypad for displaying information, wherein the keyboard and LCD are disposed on the surface of the housing and are connected to the programmed microprocessor (Fig. 26, col. 4 line 63 to col. 5 line 1-2, col. 5 line 35 to col. 6 line 11, col. 12 lines 14-66);

(d) interface means, including a port for connection to external systems and I/O channels such as terminals and a computer system, for communicating data using RF or infrared signals (Fig. 1, col. 4 line 21 to col. 6 line 11, and col. 12 lines 14-66);

(e) memory associated with a programmed microprocessor within the bar code reading device housing (col. 12 lines 14-66) to:

(1) receive at the PHPT (also called the bar code reading device) prescription information through the interface, wherein prescription information includes a recommended dosage and time to administer drugs (col. 15 line 51 to col. 16 line 17, col. 17 line 37 to col. 18 line 2, col. 26 lines 59-68, and col. 34 line 56 to col. 35 line 24); and

(2) download from memory of the PHPT data via the communications port, wherein the data includes drug information, such as drugs administered (col. 24 lines 11-36).

The remaining components of system claim 14 have been fully addressed in the rejection of method claims 1 and 7 above, and therefore the remainder claim 14 is rejected for the same reasons given above, and incorporated herein.

(I) Claims 15-17 repeat the same limitations as claims 3-4, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

(J) As per claim 18, Gombrich discloses:

a keypad on the PHPT such as a HOLD key and SEND key, wherein the keypad is within the housing of the PHPT for inputting data into the microprocessor of the PHPT (col. 12 lines 14-66, col. 16 lines 18-57, col. 27 line 16 to col. 30 line 46);

providing an alert if a particular drug administration is overdue and/or improper at a portable bar code reading device (col. 2 line 67 to col. 3 line 4 and col. 17 lines 37-59);

storing and displaying upon request six to ten previously recorded and administered PRN or other controlled drug administered and the times they were administered in the LCD of the bar code reading device (col. 2 lines 41-45, col. 3 lines 10-18, col. 3 lines 47-53, col. 5 lines 36-48, col. 14 lines 40-64, col. 16 lines 49-55, and col. 24 lines 11-36) and providing a green status light or other appropriate indication on the LCD display of the bar code reading device when a drug is administered and automatically recording the drug was administered, and pushing a button on the bar code reading device if the treatment did not occur (col. 16 line 67 to col. 17 line 29).

The remainder of claim 18 repeats the same limitations as claim 4, and is therefore rejected for the same reasons given for claim 4, and incorporated herein. The motivation for combining Leigh-Spencer within Gombrich is given above in claim 4, and incorporated herein.

(K) As per claim 20, Gombrich discloses:

(a) entering an ID and password prior to accessing the PHPT to receive information at the PHPT using software (Fig. 14, col. 16 lines 3-17, col. 17 line 37 to col. 18 line 2, col. 26 lines 59-68, col. 34 line 56 to col. 35 line 24, and col. 37 line 22 to col. 40 line 2);

(b) entering dosages by use of a key and storing a record of the most recent dosages (reads on "adding..." and "changing...") (col. 16 lines 18-57)

(c) entering a user barcode ID prior to downloading from memory of the PHPT data via the communications port (Fig. 14, col. 16 lines 3-57, col. 24 lines 11-36, and col. 37 line 22 to col. 40 line 2); and

(d) entering and recording the drug prescription as being approved for a particular patient by a pharmacist (reads on "updating patient information) (Fig. 14, col. 14 line 40 to col. 15 line 48, col. 16 lines 3-57, col. 24 lines 11-36, and col. 37 line 22 to col. 40 line 2).

The remainder of claim 20 repeats the same limitations as those in claim 1, and is therefore rejected for the same reasons given for claim 1, and incorporated herein.

7. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz (6,397,190), for substantially the same reasons given in the previous Office Action (paper number 12), and further in view of Computer Science Telecommunication Board (For the Record Protecting Electronic Health Information, Computer Science Telecommunication Board National Research Council, National Academy Press, Washington, DC, July 1997).

(A) As per claim 1, Goetz discloses a method for managing prescribed medications comprising:

(a) providing an electronic component (reads on "digital prescription carrier") capable of scheduling and tracking a number of different prescriptions and administration frequencies, wherein the electronic component includes read/write

memory and an infrared communication interface (Abstract, Fig. 1, col. 2 lines 16-25, col. 4 lines 15-45, col. 5 lines 47-52, col. 6 lines 44-52, col. 9 line 19 to col. 10 line 14, col. 17 lines 20-35, and col. 18 lines 19-38);

(b) transferring prescription information by a veterinarian (reads on "prescriber") into the electronic component through the communication interface, wherein the prescription information includes medication name and purpose, dosage, frequency, duration, and any special considerations in consuming the medication (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4);

(c) bringing an electronic component by a handler/owner (reads on "patient") to a pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48);

(d) importing prescription information from an electronic component through a communication interface at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48); and

(e) filling a prescription at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48).

Goetz fails to expressly disclose using the method for managing prescribed medications in a traditional medical environment. It is noted that the Goetz method is used in a veterinary medical environment. It is respectfully submitted that at the time the invention was made, the skilled artisan would have found it an obvious modification to use Goetz's method in a traditional medical environment with the motivation of ensuring patients are taking medications are correctly, minimizing the number of errors

in taking medications, and efficiently managing, tracking, and fulfilling prescriptions (col. 1 lines 25-57 and col. 1 line 60 to col. 2 line 25).

Claim 1 has been amended to include the newly added steps of "encrypting prescription data defining a prescription so that the data would be indecipherable without appropriate computer decryption software," "decrypting said prescription data from indecipherable form into a form that would be decipherable," and "wherein the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact."

Goetz does not expressly disclose the encryption and decryption steps. However, Goetz teaches providing security, via coding features and data encryption, to prevent unauthorized use and access to data encoded on the smart card or within the handler/owner component (col. 2 lines 38-47, col. 5 lines 20-25).

Computer Science Telecommunication Board teaches in a health care setting in a health care information system, encrypting chunks of information (components of the patient record, including text, laboratory results, and images) by a server through software when the information is transmitted over a network such as the Internet, and then decrypting the chunks of information by special access software to allow viewing of the information, wherein the software is designed to only allow accessing and viewing of the information by receipt of properly authenticated user credentials (reads on "indecipherable without appropriate computer decryption software") (pp. 86-89, pp. 106-108, pp.120-122).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the encryption and decryption techniques disclosed in Computer Science Telecommunication Board within the method taught by Goetz with the motivation of controlling the use of information in order to protect the privacy of patients (Computer Science Telecommunication Board, pg. 12, 120) and preventing unauthorized use and access to data (Goetz; col. 5 lines 20-25).

As per the recitation of "wherein the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact," it is respectfully submitted that Goetz teaches transferring prescription information by a veterinarian (reads on "prescriber") into the electronic component through the communication interface, wherein the prescription information includes medication name and purpose, dosage, frequency, duration, and any special considerations in consuming the medication (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4) and importing prescription information from an electronic component through a communication interface at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48). Goetz discloses the communication interface comprising an infrared communication link. It is respectfully submitted that infrared is a wireless communication, and therefore infrared is considered to be a form of "the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact."

(B) As per claim 2, Goetz discloses entering a password or personal identification number (PIN) to access prescription information stored in an electronic component prior to transferring data to and from the component (Fig. 33 and 35, col. 2 lines 38-46, and col. 11 lines 3-24).

(C) As per claim 3, Goetz discloses a method for managing prescribed medications including:

(a) operating a scheduling and alarm function for prescribed treatments or medications within an electronic component to generate internal values of date and time (Fig. 7, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15 lines 24-46, col. 19 lines 5-22);

(b) providing an electronic component with an input button interfaced to an alarm (Fig. 7, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15 lines 24-46, col. 19 lines 5-22);

(c) pressing an input button to accept or acknowledge administering a prescription (Fig. 7, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15 lines 24-46, col. 19 lines 5-22); and

(d) logging in memory the time/date when the prescribed medication is administered (Fig. 7, col. 2 lines 5-15, col. 4 lines 15-26, col. 8 lines 23-53, col. 13 lines 40-67, col. 14 lines 1-62, col. 15 lines 24-46, col. 19 lines 5-22).

(D) As per claim 4, Goetz discloses a method for managing prescribed medications including:

(a) providing an electronic component with an alarm, wherein the alarm is audible, visual, or tactile such as a vibrator device (col. 5 lines 25-45);

(b) inputting into an electronic component by a pharmacist, prescription information defining the desired medication, total dosage, and a schedule for administering each medication including the date and time (col. 11 line 24 to col. 12 line 16 and col. 13 lines 40-67);

(c) comparing the current time and date to the time and date tag for each active prescription stored in the electronic component (col. 13 lines 40-67); and

(d) generating an alarm when a dose of a prescription has time and date tags equal to or less than the current time and date (col. 13 lines 40-67).

(E) As per claim 5, Goetz discloses entering a password or personal identification number (PIN) to access prescription information stored in an electronic component prior to transferring data to and from the component (Fig. 33 and 35, col. 2 lines 38-46, and col. 11 lines 3-24). It is respectfully submitted that it would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized multiple passwords and/or PINs (i.e., a second access code) within the system taught collectively by Goetz and Computer Science Telecommunication Board with the motivation of improving the security of the system.

(F) As per claim 6, Goetz discloses a method for managing prescribed medications including:

(a) uploading prescribed medication data for one or more medications into an electronic component through a communication interface by a veterinarian or health care specialist (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 10 lines 30-48, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4);

(b) downloading prescribed medication data through a communication interface (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4); and

(c) filling one or more prescriptions defined by prescribed medication data (col. 6 lines 2-14 and col. 10 lines 30-48).

(G) As per claim 7, Goetz discloses a method for managing prescribed medications comprising:

(a) providing an electronic component (reads on "digital prescription carrier") capable of scheduling and tracking a number of different prescriptions and administration frequencies, wherein the electronic component includes read/write memory and a communication interface (Fig. 1, col. 2 lines 16-25, col. 4 lines 15-45, col. 5 lines 47-52, col. 6 lines 44-52, col. 9 line 19 to col. 10 line 14, col. 17 lines 20-35, and col. 18 lines 19-38);

(b) transferring prescription information into the electronic component through the communication interface, wherein the prescription information includes medication name and purpose, dosage, frequency, duration, and any special considerations in consuming the medication (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4);

(c) bringing an electronic component by a handler/owner (reads on "patient") to a pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48);

(d) importing prescription information from an electronic component through a communication interface at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48); and

(e) filling a prescription at a clinic pharmacy (col. 6 lines 2-14 and col. 10 lines 30-48).

Further, Goetz discloses entering a password or personal identification number (PIN) to access prescription information stored in an electronic component prior to transferring data to and from the component (Fig. 33 and 35, col. 2 lines 38-46, and col. 11 lines 3-24).

Claim 7 recites a "second access code" rather than a "first access code." As per this feature, note the discussion above with respect to Goetz's disclosure of the first access code. It is respectfully submitted that it would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized multiple passwords

and/or PINs within the Goetz system with the motivation of improving the security of the system.

Goetz fails to expressly disclose using the method for managing prescribed medications in a traditional medical environment. It is noted that the Goetz method is used in a veterinary medical environment. It is respectfully submitted that at the time the invention was made, the skilled artisan would have found it an obvious modification to use Goetz's method in a traditional medical environment with the motivation of ensuring patients are taking medications are correctly, minimizing the number of errors in taking medications, and efficiently managing, tracking, and fulfilling prescriptions (col. 1 lines 25-57 and col. 1 line 60 to col. 2 line 25).

As per the recitation of "said data being in a wholly intangible digital form," Goetz discloses data being transferred via an infrared communication link and stored in a database (col. 17 lines 20-35). It is respectfully submitted that data stored in a computer database is data in "digital form".

(I) Claims 8-9 and 11-13 repeat the same limitations of claims 1-6, and are therefore rejected for the same reasons given for those claims.

(J) As per claim 10, Goetz discloses an electronic component with an alarm, wherein the alarm is a vibrator device (col. 5 lines 25-45 and col. 8 lines 23-53).

(K) As per claim 14, Goetz discloses an electronic component for storing prescription data (col. 18 lines 39-48, col. 19 line 54 to col. 20 line 5, col. 20 line 50 to col. 21 20, col. 21 line 51 to col. 22 line 4, and col. 22 line 42 to col. 23 line 5) comprising:

(a) a housing (Fig. 8A and 8B, col. 9 line 50 to col. 10 line 14);

(b) a central processing unit enclosed within the housing (Fig. 8A and 8B, col. 9 line 50 to col. 10 line 14);

(c) an LCD screen included in the housing and interfaced with the CPU, and capable of displaying alphanumeric characters (Fig. 25-43, col. 5 lines 5-10, and col. 9 line 50 to col. 10 line 14);

(d) electronic circuitry enclosed in the housing and interfaced to the CPU, wherein the electronic circuitry interfaces the CPU to an external personal computer (Fig. 25-43, col. 5 lines 5-10, and col. 9 line 19 to col. 10 line 14);

(e) memory enclosed in the housing (Fig. 8A and 8B, col. 9 line 50 to col. 10 line 14); and

(f) prescription software stored in memory to be processed by the CPU (col. 7 lines 25-38 and col. 12 line 31) to enable uploading prescribed medication data for one or more medications into memory through a communication interface by a veterinarian (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6 lines 2-14, col. 10 lines 30-48, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4) and downloading prescribed medication data through a communication interface at a clinic pharmacy (col. 1 line 60 to col. 2 line 4, col. 2 lines 59-67, col. 6

lines 2-14, col. 11 line 3 to col. 12 line 16, col. 12 lines 56-61, col. 15 lines 16-22, and col. 22 line 42 to col. 23 line 4).

Goetz fails to expressly disclose using a digital prescription carrier apparatus for managing prescribed medications in a traditional medical environment. It is noted that the Goetz system is used in a veterinary medical environment. It is respectfully submitted that at the time the invention was made, the skilled artisan would have found it an obvious modification to use Goetz's system in a traditional medical environment with the motivation of ensuring patients are taking medications correctly, minimizing the number of errors in taking medications, and efficiently managing, tracking, and fulfilling prescriptions (col. 1 lines 25-57 and col. 1 line 60 to col. 2 line 25).

Computer Science Telecommunication Board teaches in a health care setting in a health care information system, encrypting chunks of information (components of the patient record, including text, laboratory results, and images) by a server through software when the information is transmitted over a network such as the Internet, and then decrypting the chunks of information by special access software to allow viewing of the information, wherein the software is designed to only allow accessing and viewing of the information by receipt of properly authenticated user credentials (reads on "indecipherable without appropriate computer decryption software") (pp. 86-89, pp. 106-108, pp.120-122).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the encryption and decryption techniques disclosed in Computer Science Telecommunication Board within the system taught by Goetz with

the motivation of controlling the use of information in order to protect the privacy of patients (Computer Science Telecommunication Board, pg. 12, 120) and preventing unauthorized use and access to data (Goetz; col. 5 lines 20-25).

(L) Claims 15-16 repeat the same limitations as claims 3-4 and 14, and are therefore rejected for the same reasons given for those claims.

(M) As per claim 17, Goetz discloses an alarm device, wherein the alert device is an audible alarm interfaced to a CPU or a vibrating device interfaced to a CPU (col. 4 lines 37-67 and col. 5 lines 5-36).

(N) As per claim 18, Goetz discloses an electronic component for storing prescription data (col. 18 lines 39-48, col. 19 line 54 to col. 20 line 5, col. 20 line 50 to col. 21 20, col. 21 line 51 to col. 22 line 4, and col. 22 line 42 to col. 23 line 5) comprising:

(a) a set of button controls positioned on the housing and interfaced to the CPU (Fig. 25-43 and col. 9 line 50 to col. 10 line 14);

(b) prescription software causing transferred prescription data to generate a schedule of dose times for a medication represented by prescription data (Fig. 8A and 8B and 25-43, col. 9 line 50 to col. 10 line 14, col. 10 lines 30-48, and col. 13 lines 40-53); and

(c) operation of button controls enabling a review of scheduled dose times for a medication, wherein the schedule is displayed on an LCD device (Fig. 8A and 8B and 25-43, col. 9 line 50 to col. 10 line 14, and col. 10 lines 30-48, and col. 13 lines 40-53).

(O) Claim 19 repeats the same limitations as claim 5, and is therefore rejected for the same reasons given for claim 5.

(P) As per claim 20, Goetz discloses:

(a) entering a password or personal identification number (PIN) to access prescription information stored in an electronic component prior to transferring data to and from the component (Fig. 33 and 35, col. 2 lines 38-46, and col. 11 lines 3-24);

(b) adding medication data for a prescription (col. 11 line 24 to col. 12 line 61); and

(c) writing and supplying data from a prescription information sheet in addition to medication administration information (reads on "updating") (col. 6 lines 15-43).

As per the step of "endowing the pharmacist with a second access code", note the discussion above with respect to Goetz's disclosure of the first access code. It is respectfully submitted that it would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized multiple passwords and/or PINs within the system taught collectively by Goetz and Computer Science Telecommunication Board with the motivation of improving the security of the system.

Affidavit

8. Applicant has submitted an Affidavit (paper number 14) to remove Goetz (6,397,190) as a reference applied under 35 U.S.C. § 103(a) in the previous Office Actions (paper numbers 4, 7, and 12). The Affidavit filed on 10 June 2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Goetz reference for the following reasons:

(A) At page 1, paragraph 1, of the Affidavit, Karl P. Schmidt states that he contributed to the invention of the subject matter claimed in this application no later than December 1997. At page 1, paragraph 3, of the Affidavit, Karl P. Schmidt states that he contributed to the reduction to practice of method steps, providing an infrared data communication interface, claimed in this application no later than December 1997. In addition, the Affidavit states in the title that it is an "AFFIDAVIT OF INVENTOR."

Firstly, Karl P. Schmidt has not been identified as an inventor in this application. Thus, the Affidavit is ineffective as it states that it is "AFFIDAVIT OF INVENTOR," when in fact Karl P. Schmidt is not an inventor. Furthermore, it is entirely unclear to the Examiner how Karl P. Schmidt contributed to the invention and contributed to the reduction to practice of method steps claimed in the invention, if Karl P. Schmidt was never identified as an inventor. Applicant is requested to address this issue of inventorship in response to this Office Action.

Secondly, the Affidavit is insufficient because Applicant provides no clear nexus between the Affidavit statement that Karl P. Schmidt contributed to the reduction to

practice of the method step, providing an infrared data communication interface, claimed in this application no later than December 1997 and the claimed subject matter. In particular, Applicant has not pointed out specific portions of the submitted printouts (Annex A-F) directly tied to the specific step, providing an infrared data communication interface.

(B) At page 13 of the 10 June 2003 response, Applicant states that in the interview between the Examiner and Applicant on 29 May 2003, it was confirmed that in *ex parte* prosecution of an application, corroborating evidence in the form of documents is not required, as per MPEP 715.07, and *Ex parte Hook and Crook*, 102 USPQ 130 (Bd. Pat. App. 1953).

In response, it is respectfully submitted that the Examiner never asked for corroborating evidence from the Applicant. **The Examiner requested that Applicant submit FACTS.** According to MPEP § 715.07, the essential thing to be shown under 37 CFR 1.131 is priority of invention and this may be done by any satisfactory evidence of the fact. FACTS, not conclusions, must be alleged. Evidence in the form of exhibits may accompany the Affidavit or declaration. Each exhibit relied upon should be specifically referred to in the Affidavit or declaration, in terms of what it is relied upon to show. In view of MPEP § 715.07, Applicant did not submit satisfactory evidence of the facts within the statements of the Affidavit. A general allegation that the invention was completed prior to the date of the reference is not sufficient. *Ex parte Saunders*, 1883 C.D. 23, 23 O.G. 1224 (Comm'r Pat. 1883). Similarly, a declaration by the inventor to

the effect that his or her invention was conceived or reduced to practice prior to the reference date, without a statement of facts demonstrating the correctness of this conclusion, is insufficient to satisfy 37 CFR 1.131. 37 CFR 1.131(b) requires that original exhibits of drawings or records, or photocopies thereof, accompany and form part of the Affidavit or declaration or their absence satisfactorily explained. For example, Applicant provides no clear nexus between the Affidavit statements that Karl P. Schmidt contributed to the reduction to practice of the method step, providing an infrared data communication interface, claimed in this application no later than December 1997 and the claimed subject matter as Applicant does not point to evidence of this feature within Annexes A-F. Thus, the Affidavit of Karl P. Schmidt is insufficient according to the requirements of MPEP § 715.07.

9. Applicant has submitted an Affidavit (paper number 15) to remove Goetz (6,397,190) as a reference applied under 35 U.S.C. § 103(a) in the previous Office Actions (paper numbers 4, 7, and 12). The Affidavit filed on 10 June 2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Goetz reference for the following reasons:

NOTE: The Examiner respectfully submits that the Affidavit of Thomas Stoll has previously been submitted by the Applicant in two separate responses, one response to a Non-Final rejection (paper number 5) and one response to a Final Rejection (paper numbers 10 and 11). The Examiner has provided detailed explanations of why the

Affidavits are ineffective to overcome the Goetz reference (see paper numbers 7 and 12). These explanations are **again** provided below for Applicant as Applicant has still failed to address the deficiencies of the Affidavit of Thomas Stoll. In addition, the Examiner has addressed new issues raised by the Affidavit filed 10 June 2003.

(A) At page 1, paragraph 1, of the Affidavit, the Applicant states that the subject matter set forth in claims 1-19 was invented no later than December 1997. Further, at pages 1-3, paragraph 3, of the Affidavit, the Applicant states that the elements and methods of claims 1-19 were reduced to practice no later than December 1997.

According to MPEP § 715.04, in general, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose. The Affidavit includes correspondence from the Applicant to Kemnitzer Design, Inc. dated 27 December 1997 (Annex B) and correspondence from the Applicant to the Applicant's patent agent dated 1 October 1998 (Annex F) which Applicant states were sent after the invention was reduced to practice (see page 6(b) and 8(f) of Affidavit). However, it is entirely unclear to the Examiner how the invention could have been reduced to practice no later than December 1997 for the following reasons:

(a) The Kemnitzer document (Annex B) states in paragraph 1, "... a product that will aid users in prescription compliance. As conceived by Medical Innovations, Inc., the product would be the size of a pager. It would have a battery powered, two line LED display that would 'remind' the user of a prescription to be taken... (emphasis added)"

Further, at paragraph 4, the document states "Medical Innovations, Inc. wishes to solicit input from potential users and prescribers prior to committing to a formal design/build program. Accordingly it has asked Kemnitzer Design, Inc. to prepare a proposal for production of a non-functional visual model (emphasis added)."

It is respectfully submitted that it is unclear how the invention was reduced to practice no later than December 1997, when according to the Kemnitzer document dated December 27, 1997, the Applicant had not committed to a formal design and was still in the process of building a non-functional, visual model. As stated above, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose. Annex B fails to show that the apparatus actually existed and worked for its intended purpose. It appears, according to Annex B, the invention had been conceived on paper and the Applicant appears to have determined what the functions of the product *would be* in the future. However, it is not clear from Annex B that the claimed invention was reduced to practice no later than December 1997.

(b) The correspondence from the Applicant to the Applicant's patent agent dated 1 October 1998 (Annex F) states in paragraph 1, "Enclosed is a block diagram, a rough sketch, and a design outline for the MedX product. These items were prepared by Karl Schmidt, an electrical engineer helping with the product's design. The product's final appearance will be different from the sketch, but the sketch may help you conceptualize the product. After the electronic design is complete an industrial designer will help create the product's overall appearance..." Further, in the Product Design Outline of

Annex F, there are features with question marks next to them (i.e., appears there are still questions in the product design) (see page 4 lines 14-17 as an example.)

It is respectfully submitted that it is unclear how the invention was reduced to practice no later than December 1997, when according to the correspondence in Annex F dated 1 October 1998, the Applicant was still completing the product's electronic design. As stated above, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose. Annex F fails to show that the apparatus actually existed and worked for its intended purpose. It appears, according to Annex F, the invention had been conceived on paper and the Applicant appears to have determined what the functions of the product *would be* in the future based on the Product Design Outline. However, it is not clear from Annex F that the claimed invention was reduced to practice no later than December 1997.

(c) In the Affidavit at page 6, Applicant states that the correspondence from Karl Schmidt to Thomas Stoll dated 25 September 1998 (Annex E) indicated that the engineer/draftsman had completed drawings of the invention.

It is respectfully submitted that it is unclear how the invention was reduced to practice no later than December 1997, when according to the correspondence in Annex E dated 25 September 1998, the Applicant had completed drawings of the invention. As stated above, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose. Annex E fails to show that the apparatus actually existed and worked for its intended purpose. It appears, according to Annex E, the Applicant had determined some components of the product.

However, it is not clear from Annex E that the claimed invention was reduced to practice no later than December 1997.

It is noted that according to MPEP § 715.04, "there are some devices so simple that a mere construction of them is all that is necessary to constitute reduction to practice." *In re Asahi /America Inc.*, 94-1249 (Fed. Cir. 1995) (Citing *Newkirk v. Lulegian*, 825 F.2d 1581, 3USPQ2d 1793 (Fed. Cir. 1987) and *Sachs v. Wadsworth*, 48 F.2d 928, 929, 9 USPQ 252, 253 (CCPA 1931). (The claimed restraint coupling held to be so simple a device that mere construction of it was sufficient to constitute reduction to practice. Photographs, coupled with articles and a technical report describing the coupling in detail were sufficient to show reduction to practice.) However, it is noted that Applicant has not provided photographs, coupled with articles and a technical report describing the claimed invention in order to establish reduction to practice no later than December 1997.

(B) At pages 1-4, paragraphs 3 and 5, of the Affidavit, the Applicant states that he reduced to practice the following elements and method steps in combination:

(a) entering a prescription into said carrier by a physician through an encryption system comprising both a hardware and software component contained within said carrier;

(b) providing within said carrier an encryption system such that said prescription information cannot be entered or altered by anyone other than a pharmacist or a physician who has access to the encryption key software;

(c) uploading encrypted information for a drug prescription into said carrier through said interface, said prescription calling for use of a selected medication at a selected dosage on a selected schedule;

(d) de-scrambling or decrypting the encrypted data so that the prescription data could be read by a pharmacist;

(e) entering data acknowledging that the prescription has been filled;

(f) encryption and decryption software capable of converting digital prescription data to an indecipherable, unreadable form, and further capable of returning encrypted data to a digital form that is readable and decipherable; and

(g) an interface for allowing the transfer of prescription data across the interface without requiring physical or electrical contact.

Applicant has not pointed out the portions of the submitted printouts (Annexes A-F) tied to the aforementioned steps and elements recited in (a)-(g) and as per the language of claims 1, 7, and 14. Applicant is respectfully requested to point out the portions of the Annexes that are related to the newly added limitations in claims 1, 7, and 14 and described in sections (a)-(g) above.

(C) At page 13 of the 10 June 2003 response, Applicant states "in the event there are differences between the subject matter set forth in the claims and the subject matter set forth in the Affidavit, then these differences - if any are found – are merely obvious variations of the claimed invention, and would have been obvious to one having ordinary skill in the applicable art." In addition, Applicant states in the Affidavit at page 3

section 4, "any differences between the method steps set forth in paragraph 3 and the method steps claimed in the pending application would have been obvious to one having ordinary skill in the art" and states in the Affidavit at page 5 section 6, "any differences between the aspects of my digital prescription carrier invention that are set forth in paragraph 4 above and the aspects that are set forth in the pending application would have been obvious to one having ordinary skill in the art."

In response, the Examiner clearly pointed out in the previous Office Action (see paper number 12, page 23, section B) that according to MPEP § 715.02, the Applicant must show **why the differences** between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of applicant's 37 CFR 1.131 evidence, prior to the effective date of the reference(s) or the activity. However, Applicant has provided no explanation of the differences between the claimed invention and the showing under 37 CFR 1.131, in view of applicant's 37 CFR 1.131 evidence, and why these differences would have been obvious. Applicant instead provided blanket statements addressing the obviousness issue. **It is requested in response to this Office Action that Applicant clarify this issue and clearly explain why the differences between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of applicant's 37 CFR 1.131 evidence, prior to the effective date of the reference(s) or the activity.**

(D) The Affidavit and correspondence, including the flowchart (Annex A), and the Kemnitzer Design correspondence dated 27 December 1997 (Annex B), are insufficient because the Affidavit and correspondence are not commensurate in scope with the claimed invention, and further the Affidavit fails to show why the differences between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of applicant's 37 CFR 1.131 evidence, prior to the effective date of the reference(s) or the activity (see MPEP § 715.02).

In particular, it is respectfully submitted that the features recited on page 5 of the Affidavit are not directly tied to the flowchart given in Annex A. At least the following features are not found in Annex A, however in the Affidavit, Applicant states he had possession of the claimed features:

i. providing a digital prescription carrier including a read/write memory and a communication interface;

ii. entering a first access code into said carrier to enable software access thereto;

iii. uploading prescription data defining a prescription into said carrier through said interface, said prescription calling for the use of a selected medication of a selected dosage on a selected schedule.

Applicant's reliance on Annex A to establish reduction to practice and to antedate the applied reference is non-persuasive as the correlation between the flowchart in Annex A and the features explicitly recited in the instant claims are not clearly established (i.e., no establishment of the elements of the flow chart that correspond with

the claims), and the Applicant fails to address why certain features are obvious when certain claimed features are not shown in Annex A.

Secondly, the evidence provided in statements in the Affidavit on pages 6-8 does not appear to have the proper support within Annex B. Applicant states that the feature of "uploading, by a prescriber, of prescription data representing a prescription into memory circuitry" is supported by Annex B stating "... the device retains history of response that can be downloaded by the pharmacist (par. 1 lines 10-11)." However, it is noted that uploading data to memory is not equivalent to downloading data from a device, and therefore fails to explicitly show the feature of uploading.

Further, Applicant states that the features of "prescription software causing uploaded prescription data to generate a schedule of dose times for a medication represented by prescription data," and "a real-time clock/calendar positioned within the housing and interfaced to the CPU," is supported by Annex B stating "This is a product that would aid users in prescription compliance... that would 'remind' the user of a prescription to be taken (par. 1 lines 2-4)." However, it is noted that Annex B fails to recite the features of prescription software causing uploaded prescription data to generate a schedule of dose times, nor does it recite anywhere a real-time clock/calendar positioned within the housing.

Also, Applicant states that the feature of an "input/output (I/O) interface circuitry positioned in said housing and interfaced to said CPU, said I/O circuitry being capable of interfacing said CPU to an external computer to exchange data therewith" is supported by Annex B stating "The device retains a history of response that can be

downloaded by the pharmacist, who can program this device through a PC" (Par. 1, lines 10-11). It is noted that Annex B fails to recite the features of input/output circuitry or the feature of interfacing with a CPU to an external computer to exchange data.

It is respectfully submitted that Applicant's reliance on Annex B to establish reduction to practice and to antedate the applied reference is non-persuasive as the correlation between the Affidavit and correspondence in Annex B and the features explicitly recited in the instant claims are not clearly established, and the Applicant fails to address why certain features are obvious when certain claimed features are not shown in Annex B (such as access codes recited in the claimed invention and the features discussed above).

It is noted that both Annex E and Annex F fail to establish a correlation between the correspondence and the claimed subject matter. The Applicant has not pointed out the specific portions of the submitted materials tied to the claimed subject matter. However, both Annex E and Annex F are dated after December 1997.

(E) The Affidavit and correspondence from Kemnitzer Design dated 27 December 1997 (Annex B) states that the invention was privately disclosed to Kemnitzer Design. However, it is respectfully submitted that Annex B fails to contain a confidentiality agreement, and further states that "Medical Innovations, Inc. wishes to solicit input from potential users and prescribers prior to committing to a formal design/build program (par. 3)." According to *Garret Corp. v. United States*, 422 F.2d 874, 878, 164 USPQ 521, 524 (Ct. Cl.1970), a document is clearly a printed publication when it is distributed

to commercial companies without restriction on use, while distribution to government agencies and personnel alone may not constitute publication. Further, according to Annex B, potential users and prescribers provided input prior to a formal design/build program, and the Affidavit failed to include information on whether those potential users and prescribers signed confidentiality agreements. Therefore, Applicant has failed to provide documentation within the Affidavit stating that both Kemnitzer Design and potential users and prescribers were under confidentiality agreements, and it appears Annex B was disclosed to the public.

It is noted that at page 9, paragraph 9, of the Affidavit, Applicant states that the invention was never offered for sale or publicly disclosed, nor has Applicant ever publicly disseminated any information regarding my invention. However, Applicant requested proof that confidentiality agreements were signed between potential users and prescribers, as it is noted that in Annex B, Applicant stated that "Medical Innovations, Inc. wishes to solicit input from potential users and prescribers prior to committing to a formal design/build program (par. 3)." Therefore, it is assumed that this information was solicited from potential users and prescribers, and thus required confidentiality agreements.

(F) The Affidavit includes a copy of a printout from the corporations database of the Missouri Secretary of State, verifying an incorporation dated 9 May 1997 (Annex C) and a copy of an IRS Form 2553 dated 14 March 1998 (Annex D). It is respectfully submitted there is no clear nexus between the materials and the claimed subject matter.

In particular, Applicant has not pointed out specific portions of the submitted printouts directly tied to the specific elements or features that are being claimed. For example, Applicant has not pointed out the portions of the submitted printouts tied to the step of "uploading prescription data..." as per the language of claims 1, 7, and 14 and the steps of "entering a first access code" and "entering a second access code" as per the language of claims 2, 7, and 20. Furthermore, although the printouts are acknowledged and entered into the record by the Examiner, it is noted there is nothing related to the language recited in the instant claims within the submitted printouts, and therefore the printouts appear to be irrelevant to the issues at hand.

(G) Applicant's reliance on the Affidavit filed 10 June 2003, including Annex A – Annex F, to show actual reduction to practice is non-persuasive for the reasons given above in sections A-F. Therefore, constructive reduction to practice is the filing date of the application, 21 January 2000, and reduction to practice has not been shown to be earlier than 21 January 2000. It is noted that December 1997 appears to be when the invention was conceived based on the documents submitted, and if conception occurred in December 1997, then the Applicant would need to show due diligence from December 1997 to the date of filing, 21 January 2000. However, if the Applicant properly shows actual reduction to practice occurred no later than December 1997 based on MPEP § 715.02, MPEP § 715.04, and the discussion above, the requirement to show due diligence will be removed.

(G) It is noted that the last correspondence submitted in the Affidavit occurred 1 October 1998 (Annex F). However, the present application was not filed until 21 January 2000. It is respectfully submitted that an explanation as to what occurred during the time period between 1 October 1998 and 21 January 2000 has not been included within the Affidavit.

Response to Arguments

10. Applicant's arguments filed 10 June 2003 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appear in the response filed 10 June 2003.

(A) At pages 10-11 of the 10 June 2003 response, Applicant argues that the features of claim 1, namely, uploading prescription data defining a prescription into said carrier through said interface, and downloading said prescription data through said interface at said pharmacy, are not taught by the applied references.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 10 June 2003 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Gombrich, Leigh-Spencer, and/or the Computer Science Telecommunication Board based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office

Action and in the prior Office Actions (paper numbers 4 and 12), and incorporated herein. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Furthermore, the Examiner respectfully notes that neither of the Gombrich, Leigh-Spencer, and/or the Computer Science Telecommunication Board references were ever applied as references under 35 U.S.C. 102 against the pending claims. As such, the Examiner respectfully submits that the issue at hand is not whether the applied prior art specifically teaches the claimed features, *per se*, but rather, whether or not the prior art, when taken in combination with the knowledge of average skill in the art, would put the artisan in possession of these features. Regarding this issue, it is well established that references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by

decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i) obviousness does not require absolute predictability;

(ii) non-preferred embodiments of prior art must also be considered; and

(iii) the question is not express teaching of references, but what they would suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory limitation as to the number of references that may be used to demonstrate obviousness...not what references expressly state but what they would reasonably suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

In this case, each limitation recited in claims 1-20 has been addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Gombrich, Leigh-Spencer, and/or the Computer Science Telecommunication Board

based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as clearly detailed in the remarks and explanations given above, and incorporated herein.

As such, it is respectfully submitted that Applicant appears to view the applied references in a vacuum without considering the knowledge of average skill in the art.

In reference to Applicant's specific arguments that Gombrich and Leigh-Spencer fail to disclose uploading prescription data defining a prescription into said carrier through said interface and downloading said prescription data through said interface at said pharmacy, it appears that Applicant's statements are misdescriptive of the full teachings of the combination of Gombrich and Leigh-Spencer. Gombrich discloses providing a portable handheld patient terminal (PHPT) with a bar code reader to provide the main data collection component of patient identification information, wherein the PHPT allows storage of data relating to patients in memory (reads on "write"), wherein the PHPT utilizes infrared (IR) transmission/reception by an infrared transmitter/receiver arrangement or interface to transmit or send data stored in memory (reads on "read) (col. 3 line 59 to col. 4 line 20, col. 5 line 18 to col. 6 line 11, col. 10 line 57 to col. 11 line 5, col. 12 lines 14-66, col. 23 line 11-36), receiving at the PHPT (also called the bar code reading device) prescription information through the interface, wherein prescription information includes a recommended dosage and time to administer drugs entered by a staff member, secretary, or nurse (reads on "by a prescriber") (col. 15 line 51 to col. 16 line 17, col. 17 line 37 to col. 18 line 2, col. 26 lines 59-68, and col. 34 line 56 to col. 35 line 24), downloading from memory of the PHPT data via the communications port,

wherein the data includes drug information, such as drugs administered (col. 24 lines 11-36). Further, Gombrich includes the input and output of data using infrared communication or RF communication (col. 10 line 57 to col. 11 line 51, col. 24 lines 11-36), wherein the RF signals allow for real time data transmission using an RF transceiver and antenna arrangement. The input and output of data using infrared or RF signals or infrared are wireless as evidenced by Gombrich (col. 23 15-20), and thus these wireless communication protocols are considered to be a form of "the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact."

It is respectfully submitted that Gombrich taken collectively with Leigh Spencer and the Computer Science Telecommunication Board teach the features of claim 1, and therefore the rejection is maintained.

In response to applicant's argument that Leigh-Spencer teaches away from the combination of references, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

(B) At pages 10-11 of the 10 June 2003 response, Applicant argues that the features of claim 7, namely, said data being in wholly intangible form and the steps of encrypting and decrypting prescription data, are not taught by the applied references.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 10 June 2003 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Gombrich, Leigh-Spencer, and/or the Computer Science Telecommunication Board based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Actions (paper numbers 4 and 12), and incorporated herein. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Furthermore, the Examiner respectfully notes that neither of the Gombrich, Leigh-Spencer, and/or the Computer Science Telecommunication Board references were ever applied as references under 35 U.S.C. 102 against the pending claims. As such, the Examiner respectfully submits that the issue at hand is not whether the applied prior art specifically teaches the claimed features, *per se*, but rather, whether or not the prior art, when taken in combination with the knowledge of average skill in the art, would put the artisan in possession of these features. Regarding this issue, it is well established that references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i) obviousness does not require absolute predictability;

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to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory limitation as to the number of references that may be used to demonstrate obviousness...not what references expressly state but what they would reasonably suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

In this case, each limitation recited in claim 7 has been addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Gombrich, Leigh-Spencer, and/or the Computer Science Telecommunication Board based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as clearly detailed in the remarks and explanations given above, and incorporated herein.

As such, it is respectfully submitted that Applicant appears to view the applied references in a vacuum without considering the knowledge of average skill in the art.

(C) Applicant's remaining arguments given at pages 11-13 of the response filed 10 June 2003 rely upon or rehash the issues addressed above, and are therefore moot in view of the responses given in sections 10(A)-10(B) above, and incorporated herein.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches automated networked service request and fulfillment system and method (5,995,939), method, apparatus, and system for verification of human medical data (5,876,926), and an article about security in healthcare information systems – current trends (Smith).

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-

3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

14. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9306	[Official communications; including After Final communications labeled "Box AF"]
(703) 746-8374	[Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB
August 20, 2003

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600